JUL 16 2008

SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Indication Expansion – ENDOBUTTON Continuous Loop Fixation Devices

Date Prepared: April 16, 2008

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover MA, 01810

B. Company Contact

Christina Flores

Regulatory Affairs Specialist

Phone: (508) 261-3705

FAX: (210) 690-2559

C. Device Name

Trade Name: ENDOBUTTON Continuous Loop

Common Name: Suture Retention device, Non-absorbable (polyester) surgical suture

Classification Name: Fastener, Fixation, Non-degradable, Soft tissue
Non-absorbable surgical suture

D. Predicate Devices

The indication for fixation of tendons and ligaments in orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) reconstruction and acromioclavicular joint separations due to coracoclavicular ligament disruptions is substantially equivalent to the currently marketed indications for use of the following legally marketed devices in commercial distribution: the ConMed Linvatec XO Button™ (cleared via K070780) and the Arthrex Tightrope™ Acromioclavicular (AC) Device (cleared via K052776).

E. Description of Device

ENDOBUTTON CL

The ENDOBUTTON CL is a machined titanium implant assembled with a continuous loop of polyester tape. It is oblong in shape with four holes through which suture is threaded. The polyester loop is preattached to the center holes. The device is designed to provide cortical fixation in the repair of tendons and ligaments. The design of the ENDOBUTTON allows for the device to be endoscopically delivered from a single access point. The device is available with premeasured loops of tape ranging from 20mm-50mm to accommodate different graft sizes.

ENDOBUTTON

The ENDOBUTTON is a machined titanium implant designed to provide cortical fixation in the repair of tendons and ligaments. It is oblong in shape with four holes through which suture is threaded. The design of the ENDOBUTTON allows for the device to be endoscopically delivered from a single access point.

F. Intended Use

The intended use of the currently available ENDOBUTTON Fixation Devices remains unchanged. The Smith & Nephew ENDOBUTTON Fixation Devices are used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament reconstruction and acromioclavicular joint separations due to coracoclavicular ligament disruptions.

G. Comparison of Technological Characteristics

There are no changes to the existing devices. Technological Characteristics remain the same.

H. Summary Performance Data

The performance testing conducted demonstrates substantial equivalence to the Arthrex Tightrope™ Acromioclavicular (AC) Device, cleared via K052776. The testing also demonstrates that the expanding the indications for use do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew
% Endoscopy Division
Ms. Christina Flores
Regulatory Affairs Specialist
150 Minuteman Road
Andover, MA 01810

JUL 16 2008

Re: K081098
Trade/Device Name: Endobutton Continuous Loop (CL)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR, MBI, HWC
Dated: April 16, 2008
Received: April 17, 2008

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081098

Device Name: ENDOBUTTON Continuous Loop (CL)

Indications For Use:

The Smith & Nephew ENDOBUTTON Continuous Loop is used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) reconstruction and acromioclavicular joint separations due to coracoclavicular ligament disruptions.

Prescription Use ___x_____ AND/OR Over-The-Counter Use No

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brown

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081098